

## REMARKS

Presently claims 1-5, 7-8, and 10-12 are pending in this application. Claim 1 is amended. Applicant will now respectfully address the Examiner's rejections.

### Rejections under 35 U.S.C. 101

Claim 1 is rejected for allegedly reciting non-statutory subject matter. In response, Applicant respectfully amends claim 1 as suggested by the Examiner.

### Rejections under 35 U.S.C. 112, first paragraph

Claim 1 is rejected because the specification allegedly does not provide enablement for permanently disconnecting an incus and stapes. In response, Applicant again respectfully asserts that it is well known in the art that disconnection of the ossicular chain does not naturally heal or reconnect. In response to the Examiner's contention that Ball teaches a natural healing that refutes Applicant's assertion, Applicant respectfully provides the following.

Col. 10, lines 47-51 of Ball, which is the portion of Ball that is cited by the Examiner to allegedly teach "natural healing," describes one of several steps performed during an implanting procedure. Applicant respectfully submits that this portion of Ball should not be read separately from the description of the complete process of implanting, which begins on line 44 of Ball.

The steps of implanting as described by Ball (beginning at line 44 of Col. 10) include a) separating the stapes HH from the incus HM, b) positioning a portion of the stapes within the opening 36 by slipping the O-shaped transducer around the stapes HH, c) **returning** the separated ossicles (namely the stapes HH and the incus HM) to their natural position, and d) **surgically connecting** the tissue of the ossicles, wherein a healing re-connection of the incus HM and stapes HH occurs via the surgical connection.

Accordingly, Applicant respectfully asserts that the returning and connecting steps c) and d) are necessary to reconnect the two ossicles which have been separated before in step a. Thus, the passage of Ball cited by the Examiner does not read on self-healing. Instead, this passage describes the prerequisites for a surgical reconnection, including a returning of the ossicles to their natural position and fixing of the ossicles in this position. As is at least implicitly taught here in Ball, and as is well known in the art, reconnection necessitates surgical steps, namely steps like the positioning and connecting of steps c) and d) above, and does not take place if the ossicles are not returned to their natural position and fixed in the position thus obtained, via sewing together, gluing or some other surgical equivalent.

Accordingly, Applicant again respectfully submits that permanent disconnection of the incus and stapes as shown in Figure 2 of Applicant's Drawings is inherently and necessarily permanent, and thus, Applicant's specification need not describe a "means" for preventing connective tissue healing and re-connection between an incus and stapes..

#### Rejections under 35 U.S.C. 102(b)/103(a)

Claims 1-4, 8, and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 5,624,376 to Ball ("Ball" hereinafter) or being obvious over Ball in view of United States Patent No. 6,540,662 to Kroll ("Kroll" hereinafter) or United States Patent No. 6,585,637 to Brillhart ("Brillhart" hereinafter). Applicant respectfully traverses.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Furthermore, for an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art and

that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

Applicant's amended claim 1 recites *inter alia*,

“the sound receiver being rigidly fixed to malleus or incus in a manner that permanently interrupts the ossicular chain such that the incus and stapes, or any replacement thereof, are permanently disconnected and the incus is allowed move independently from the stapes or any replacement thereof.”

Applicant first asserts that Ball does not teach a sound receiver being rigidly fixed to malleus or incus in a manner that permanently interrupts the ossicular chain *such that the incus and stapes, or any replacement thereof, are permanently disconnected and the incus is allowed move independently from the stapes or any replacement thereof.* Instead, referring to Figures 8 and 9, Ball teaches an ossicular chain that is uninterrupted between the tympanic membrane CC and oval window EE at least in part due to the incus being fixed to a replacement stapes. Thus, the incus is not permanently disconnected to the stapes *or any replacement thereof*, as is required by Applicant's claim 1. In addition, as the replacement stapes is connected at both of its ends, this replacement cannot move independently of the incus, as is also required by Applicant's claim 1. Furthermore, Applicant respectfully notes that the only disconnection taught in Ball is a temporary disconnection performed during a surgical operation. The temporary disconnection is first opened and then closed via the surgical operation. Applicant respectfully points out that this disconnection taught in Ball is *necessarily temporary, as any permanent disconnection of the Ball system would render the patient **unable to hear**.* Such a conclusion is evidenced by col. 6, lines 7-9 of Ball, which states that, “the mechanical vibrations of the

floating mass are transformed into a vibration of the vibratory structure allowing the patient to hear.”

Referring now to any combination between Ball and Kroll or Brillhart, Applicant again notes that any break in the ossicular chain in Ball would render Ball inoperable for its intended purpose of allowing a user to hear (again, please see col. 6, lines 7-9 of Ball). Hearing via the vibration taught here requires an intact ossicular chain. Accordingly, if one were to modify Ball by disconnecting the incus from the stapes, which would be the result of the Examiner’s proposed combination of Ball with either Kroll or Brillhart sound/vibration from the floating mass magnet 100 of Ball to the oval windows EE would be interrupted and the hearing ability of the patient would not be improved but completely disabled.

Applicant respectfully notes that, according to MPEP 2143.01 V, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. As permanent disruption of the ossicular chain would render Ball unsatisfactory for its intended purpose of allowing a patient to hear, the Examiner’s proposed combination of Ball with either Kroll or Brillhart is respectfully improper.

As Ball does not teach every element of claim 1 and claims 2-4, 8, and 10-11 that depend therefrom, and one of ordinary skill at the time of Applicant’s invention would not have a motivation to modify or combine Ball with either Kroll or Brillhart, Applicant respectfully submits that *prima facie* obviousness does not exist with regards to claims 1-4, 8, and 10-11.

In addition to the above, Applicant respectfully points out that Ball does not teach a “sound receiver” as is recited in Applicant’s claims. On page 4, lines 5-9 of the Office Action, the Examiner rejects our argument concerning the difference between a sound receiver and a sound transducer. Ball is very precise in describing a receiver when a receiver is used and a transducer when a transducer is used. The examiner simply argues

"a vibrational transducer as disclosed in Ball '376 can be considered a sound receiver." This is contrary to the knowledge of a man of ordinary skill the art and contrary to the teaching of Ball. There is no similar instruction in Ball, which very clearly differentiates between the two devices.

The electric output of a microphone is rather small (too small to be directly used to drive a sound transducer) and an amplifier is needed to increase the signal amplitude. Such an amplifier is described in Ball among others on col. 18, line 10 and Fig. 25, ER-7 AMP following ER-7 MICROPHONE.

It is known in the art that electric signal produced by a sound receiver is too small to drive a sound transducer and that no audible output is obtained from the sound transducer if there is insufficient driving power applied. A man of ordinary skill in the art would therefore know that an amplifier is needed to drive a sound transducer. However, contrary to the sound receiver (microphone) which must be connected with the input of the amplifier, the sound transducer must be connected with the output of the amplifier, see Ball, col. 22, line 24.

In Fig. 22, Ball precisely describes the use of i) a sound receiver ER-7 connected to the input of the amplifier ER-7 and furthers to the B&K 2006 amplifier and of ii) the sound transducer ER-2, connected with the output of CROWN STEREO AMP. In a hearing aid or hearing system the complete amplifier arrangement must be reversed if a sound transducer is intended to take the function of a microphone. This is why Ball clearly distinguishes between function of a sound transducer and a sound receiver. Accordingly, Applicant respectfully submits that the argument of equivalence set forth by the Examiner is not appropriate. Applicant further evidences this submission by respectfully asserting that replacement of a sound receiver with a sound transducer in any of Ball's embodiment would result in an unachieved hearing function. More specifically, Ball does not teach a) a fixing the sound receiver to malleus or incus, and/or b) a permanent disconnect of the ossicular chain therebehind. Thus, if in step a) the sound receiver is replaced by a sound transducer, no hearing function is obtained either because the sound transducer would only

move parts which are not connected with the middle ear. If step b) is not performed it would not be possible to actively move the stapes (with the output power of the amplifier necessary in any hearing system) without moving the sound receiver and creating a feed back.

Applicant still further asserts that any combination of Ball, Kroll, and Brillhart, also does not teach a sound receiver that “has feedlines for a connection with a signal processing unit,” as has now been amended into Applicant’s claims. This amendment has basis at page 4, lines 6 and 7 of Applicant’s Specification.

Rejections under 35 U.S.C. 103(a)

Claim 5 is rejected under 35 U.S.C. 103(a) as being obvious over Ball in view of Kroll or Brillhart and United States Publication No. 2002/0138115 to Baumann (“Baumann” hereinafter). Applicant respectfully traverses.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art and that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

As claim 5 depends from claim 1, for at least the reasons discussed in the 102 remarks above, Ball does not teach every element of claim 5. Since Baumann does not remedy the above discussed deficiencies of Ball, the proposed combination of Ball Kroll or Brillhart and Baumann fails to teach or suggest all of the limitations of claim 5. As the proposed combination of Ball Kroll or Brillhart and Baumann does not teach every element of claim 5, clearly, one of ordinary skill at the time of Applicant’s invention would not have a motivation to modify or combine Ball Kroll or Brillhart and Baumann, or a reasonable likelihood of success in forming the claimed invention by modifying or

combining Ball Kroll or Brillhart and Baumann. For at least these reasons, Applicant respectfully submits that *prima facie* obviousness does not exist with regards to claim 5.

Claims 7 and 12 are also rejected under 35 U.S.C. 103(a) as being obvious over Ball in view of Kroll or Brillhart, United States Patent No. 5,531,787 to Lesinski et al. (“Lesinski” hereinafter), and United States Patent No. 6,398,717 to Leysieffer et al. (“Leysieffer” hereinafter). Applicant respectfully traverses.

As claims 7 and 12 depends from claim 1, for at least the reasons discussed in the 102 remarks above, Ball does not teach every element of claims 7 and 12. Since neither Lesinski nor Leysieffer remedy the above discussed deficiencies of Ball, the proposed combination of Ball, Kroll or Brillhart, Lesinski, and Leysieffer fails to teach or suggest all of the limitations of claims 7 and 12. As the proposed combination of Ball, Kroll or Brillhart, Lesinski, and Leysieffer does not teach every element of claims 7 and 12, clearly, one of ordinary skill at the time of Applicant’s invention would not have a motivation to modify or combine Ball, Kroll or Brillhart, Lesinski, and Leysieffer, or a reasonable likelihood of success in forming the claimed invention by modifying or combining Ball, Kroll or Brillhart, Lesinski, and Leysieffer. For at least these reasons, Applicant respectfully submits that *prima facie* obviousness does not exist with regards to claims 7 and 12.

Conclusion

The rejections herein overcome. Entry of the present Response with Amendment and prompt issuance of a Notice of Allowance are respectfully requested.

Applicant hereby petitions for any necessary extension of time required for consideration of this Response.

Please charge any fees due with respect to this Response, or otherwise regarding the application, to Deposit Account 06-1130 maintained by Applicant's attorneys.

The Office is invited to contact Applicants' attorneys at the below-listed telephone number regarding this Response or otherwise concerning the present application.

Respectfully submitted,

By: /Daniel R. Gibson/  
Daniel R. Gibson  
Registration No. 56,539  
CANTOR COLBURN LLP  
20 Church Street  
22<sup>nd</sup> Floor  
Hartford, CT 06103  
Telephone: 860-286-2929  
Facsimile: 860-286-0115  
Customer No. 23413

Date: September 22, 2008